UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
SOUTHERN DIVISION

GENUS LIFESCIENCES, INC., Plaintiff, v. U.S. FOOD AND DRUG ADMINISTRATION, et al., Defendants	)	Case No. 8:20-cv-3282-PX

LANNETT CO., INC.'S MEMORANDUM IN SUPPORT OF UNOPPOSED MOTION TO INTERVENE

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I. INTRODUCTION

Proposed intervenor Lannett Co., Inc. ("Lannett") submits this memorandum in support of its motion to intervene as a defendant in this action pursuant to Federal Rule of Civil Procedure 24. Lannett seeks to participate fully as a defendant in this action.

Plaintiff Genus Lifesciences, Inc. ("Genus") is asking the Court to order the U.S. Food and Drug Administration ("FDA") to initiate proceedings to withdraw approval of Lannett's New Drug Application ("NDA") for Numbrino because of an alleged "untrue statement of material fact." Compl. ¶¶ 72, 76 (Dkt. 1). Because Lannett has a significant interest in maintaining approval of its drug, Numbrino, it has a right to intervene in this action pursuant to Fed. R. Civ. P. 24(a), as set forth below. Additionally, Lannett meets the requirements for permissive intervention under Fed. R. Civ. P. 24(b), as also set forth below.

Lannett has conferred with counsel for Plaintiff Genus and counsel for the Federal Defendants regarding this motion. Counsel for Genus stated Genus will not oppose intervention. Counsel for the Federal Defendants stated the Federal Defendants take no position on Lannett's motion to intervene.

II. BACKGROUND

Lannett is a pharmaceutical company that develops and sells various brand-name and generic drugs. Lannett has a significant right and interest in this lawsuit because Lannett holds the approved NDA that Genus seeks in its complaint to have this Court order FDA to begin proceedings to unwind. If Genus were to receive the relief it seeks and Lannett's approval for Numbrino were rescinded, Lannett's interests would be injured in multiple ways. First, and most obviously, if approval were rescinded, Lannett would no longer have legal authorization to market Numbrino. And it could take years to get it back: in view of Genus's active period of "new

chemical entity" exclusivity ("NCEE"), Lannett would not be permitted to submit a new application to market any cocaine hydrochloride product until after the NCEE submission bar expires on December 14, 2022. Second, the delay would erode the current competitive advantage that Lannett enjoys by virtue of having sought FDA approval before Genus's period of exclusivity. Such revoked approval would permit other applicants to apply for approval at the same time as Lannett. Once the NCEE expires, any drug manufacturer will be allowed to submit generic-drug applications for the cocaine hydrochloride drug product. This would eliminate Lannett's current competitive advantage gained through its correct and accurate submission of its NDA and approval thereof by FDA.

III. PROCEDURAL HISTORY

In September 2017, the FDA received Lannett's 21 U.S.C. § 355(b)(2) NDA for a cocaine hydrochloride nasal spray drug product. *See* Compl. ¶ 36; Cavanaugh Declaration, attached as **Exhibit A,** ¶ 3. While processing Lannett's application, FDA issued a Complete Response Letter ("CRL") requesting additional information from Lannett. *See* Compl. ¶ 38; Ex. A at ¶ 3. This information was duly supplied, and FDA approved Lannett's NDA on January 10, 2020. *See* Compl. ¶ 56; Ex. A at 3; NDA Approval Letter, dated January 10, 2020, attached as **Exhibit B**.

Numbrino's NDA was originally submitted by Cody Laboratories, a wholly-owned subsidiary of Lannett. *See* Ex. A ¶ 4. At the time, Cody Laboratories was based in Cody, Wyoming. *See id.;* Lannett Annual Report 2019, attached as **Exhibit C**. Once requisite stability data and all other supportive data and information had been obtained from another Lannett facility, located in Carmel, New York, and after FDA approved Lannett's 505(b)(2) application, Lannett informed FDA of its intention to change manufacturing locations, and Lannett submitted the

required data by way of a "Changes Being Effected" procedure authorized by FDA regulation and guidance. *See* Ex. A ¶ 4.

IV. ARGUMENT

Lannett is entitled to intervene as of right in this case. *See* Fed. R. Civ. P. 24(a). Lannett also meets the requirements for permissive intervention under Fed. R. Civ. P. 24(b). Lannett has standing to intervene as a defendant, and this motion is timely filed. As detailed below, Lannett has significant interests in this case which are not adequately represented by the current Federal Defendants. Additionally, there will be no prejudice to including Lannett in the case at this early stage of the proceedings.

A. Article III Standing

Lannett has Article III standing to intervene in this case. *See CX Reins. Co. v. Singer Realty, Inc.*, No. CCB-15-3056, 2018 WL 271984, at *3 (D. Md. Jan. 3, 2018) (citing *Crossroads Grassroots Policy Strategies v. Fed. Election Comm'n*, 788 F.3d 312, 316 (D.C. Cir. 2015)). This includes injury in fact, causation, and redressability. *See id.* If Genus is successful in this suit and Lannett were to lose its NDA, it would also lose all of the market share and profits that currently result from its status as an approved drug. This is sufficient to prove injury in fact. *See Crossroads*, 788 F.3d at 317 (stating "[o]ur cases have generally found a sufficient injury in fact where a party benefits from agency action, the action is then challenged in court, and an unfavorable decision would remove the party's benefit."). This injury is clearly linked to the relief sought by Genus. As such, Lannett has established sufficient standing to intervene in this action.

B. Intervention of Right

Fed. R. Civ. P. 24(a) permits intervention as of right when a party has an interest that may not be fully protected by the parties already involved in the litigation. The Rule provides that

> the court must permit anyone to intervene who . . . claims an interest relating to the property or transaction that is the subject of the action, and is so situated that disposing of the action may as a practical matter impair or impede the movant's ability to protect its interest, unless pre-existing parties adequately represent that interest.

Id. A motion to intervene as of right depends on (1) the timeliness of the motion; (2) whether the would-be-intervenor has an interest in the subject matter of the underlying action; (3) whether denying the motion would "impair or impede the applicant's ability to protect its interest; and (4) whether the already-named parties to the action fully represents the interest of the applicant. *See Hous. Gen. Ins. Co. v. Moore*, 193 F.3d 838, 839 (4th Cir. 1999) (citing Fed. R. Civ. P. 24(a)); *Newport News Shipbuilding & Drydock Co. v. Peninsula Shipbuilders' Ass'n*, 646 F.2d 117, 120 (4th Cir. 1981). These factors should be liberally construed in favor of intervention. *See Teague v. Bakker*, 931 F.2d 259, 261 (4th Cir. 1991); *In re Sierra Club*, 945 F.2d 776, 779-80 (4th Cir. 1991); *United Guar. Residential Ins. Co. of Iowa v. Phila. Sav. Fund Soc'y*, 819 F.2d 473, 475 (4th Cir. 1987).

This District has recognized the interests of parties in analogous situations and granted their motions to intervene. *See Otsuka Pharm. Co. v. Burwell*, Civil Action No. GJH-15-852, 2015 WL 3442013, at *1 n.2 (D. Md. May 27, 2015) (noting several drug companies allowed to intervene as defendants in action against FDA seeking to overturn their approvals); *Nat. Res. Def. Council v. U.S. Env't Protection Agency*, Civil Action No. RDB 03-2444, 2005 WL 1241904, at *1 (D. Md. May 24, 2005) (noting Syngenta, Kansas Corn Growers, and CropLife allowed to intervene as defendants in action seeking to rescind approval of their products); *see also Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1074 (D.C. Cir. 1998) (overturning the lower court's denial of Pharmacia & Upjohn Co.'s motion to intervene); *Hi-Tech Pharmacal Co. v. U.S. Food & Drug Admin.*, 587 F. Supp. 2d 1, 7 (D.D.C. 2008) (drug manufacturer allowed to intervene as

defendant in action seeking to block FDA approval of its application); *Biovail Corp. v. U.S. Food & Drug Admin.*, 519 F. Supp. 2d 39, 42-43 (D.D.C. 2007) (similar); *Apotex Inc. v. U.S. Food & Drug Admin.*, 508 F. Supp. 2d 78, 80 n.2 (D.D.C. 2007) (similar). Lannett meets all four factors for intervention.

1. The Motion to Intervene as of Right Is Timely.

Based on the status of this case, Lannett's motion is timely. Timeliness is a "cardinal consideration" for a motion to intervene. *See Hous. Gen.*, 193 F.3d at 839 (citing *Brink v. DaLesio*, 667 F.2d 420, 478 (4th Cir. 1981)). This case was filed on November 12, 2020, about a month before this motion was submitted. *See* Order at 1, *Nat. Res. Def. Council*, 2005 WL 1241904, ECF No. 27 (granting motions to intervene submitted within six weeks of the action being filed). At this time, nothing more than the complaint and attorney appearances has been filed, so there is no risk of prejudice to Genus should Lannett's motion be granted. Since the case is in its infancy, Lannett's motion to intervene has been submitted in a timely manner.

2. Lannett Has Significant Legally Protected Interests in the Case.

Lannett has significant legally protected interests in preserving its NDA approval for Numbrino, approval which Genus argues Lannett should lose. Courts have previously recognized that agency approval to sell a product is a substantial protectable interest. *See Nat. Res. Def. Council*, 2005 WL 124441904, at *1 (permitting intervention when interest was EPA approval to sell a pesticide); *Apotex*, 508 F. Supp. 2d at 80 n.2 (stating that a pharmaceutical company "easily satisfies the requirements" of Fed. R. Civ. P. 24(a) by virtue of its interest in FDA approval of its product). And, a party to the administrative proceedings that are being challenged has an interest in seeing the agency action upheld. *See In re Sierra Club*, 945 F.2d at 779. The central allegations in this case are that Lannett made a material untrue statement in its NDA and that FDA ignored

that statement, allegedly in violation of law. Lannett vigorously disputes these allegations (which wrongfully impugn its integrity in addition to the integrity of the regulatory personnel at the company which enjoy an impeccable reputation with the FDA) and desires to defend against them in this lawsuit. The validity and longevity of its NDA is of great interest to Lannett as a matter of both business and finance.

3. This Action Threatens Lannett's Interests.

Genus seeks an order compelling FDA to investigate, and possibly withdraw, Lannett's approved NDA for Numbrino. This could result in a loss of significant profits for Lannett and diminish Lannett's ability to recoup its significant investments incurred in bringing Numbrino to market. *See* Ex. A ¶¶ 5-6. Lannett may be forced to wait until after the expiration of the Genus NCEE to submit a new application and, in 2022, compete with other potential generic drug manufacturers. *See United Guar.*, 819 F.2d at 475 (finding a party's interest would be threatened by a financial loss); *see also Jones v. Koons Auto., Inc.*, 752 F. Supp. 2d 670, 690 (D. Md. 2010) (economic interest coupled with a particular right is sufficient to support intervention) (collecting cases). In addition to Lannett losing customers and sales during the period of Genus's NCEE, if Lannett were to lose FDA approval over Numbrino, that loss of approval would threaten to deprive Lannett of the market share it has earned. *See* Ex. A ¶¶ 6-8; *Mova Pharm.*, 140 F.3d at 1075-76 (finding a would-be-intervenor's interests were at risk when there was a chance of lost market share).

In addition to its monetary interests, the allegations in the complaint attempt to smear Lannett's reputation in the industry. Lannett has been in business for over 70 years, has an excellent reputation with the FDA, and has never been accused of anything close to the wrongful

conduct alleged in the complaint. Lannett vigorously disputes that it ever made any misrepresentations to the FDA and should be entitled to clear its name.

4. FDA Is Unable to Adequately Represent Lannett's Interests.

Lannett's interests in this case may not be adequately represented by the Federal Defendants. A proposed intervenor is only required to show that representation of its interests "may be inadequate," and some shared interests does not guarantee that representation will be adequate. *Trbovich v. United Mine Workers*, 404 U.S. 528, 538 n.10 (1972); *see also United Guar.*, 819 F.2d at 475. Indeed, "the burden of making that showing should be treated as minimal." *Trbovich*, 404 U.S. at 538 n.10. Lannett easily meets this burden. Whereas Lannett is concerned with preserving its NDA, FDA may have concerns that extend beyond Lannett. *See United Guar.*, 819 F.2d at 476. Indeed, there may be reasons beyond this case that will guide FDA's litigation strategy.

The Fourth Circuit has recognized that an agency's position is defined by its own view of the public interest, and not necessarily the interest of the intervenor. *See Feller v. Brock*, 802 F.2d 722, 730 (4th Cir. 1986) (citing *Trbovich*, 404 U.S. at 538-39). Here, the FDA may have interests that go beyond this suit and may influence the defenses and arguments it asserts. Further, if the FDA decided not to appeal an adverse decision, Lannett would have no other options to participate to defend its interests. This is not an imagined threat: the FDA has previously failed to pursue appeals for decisions that adversely affected a pharmaceutical company in order to pursue a different agency goal. *See* Unopposed Voluntary Motion to Dismiss Appeal at 1, *Depomed, Inc. v. U.S. Dep't Health & Human Servs.*, No 14-5271, 2014 WL 5838247 (D.C. Cir. Nov. 7, 2014) (seeking to dismiss its own appeal).

Because this motion to intervene is timely, and Lannett has significant protectable interests in the case that are not adequately represented by the existing defendants, Lannett is entitled to intervene as of right.

C. Permissive Intervention

Lannett also meets the requirements for permissive intervention pursuant to Fed. R. Civ. P. 24(b). Permissive intervention is appropriate where there is a claim or defense with a common question of law or fact and intervention would not result in undue delay. *See Makhteshim Agan of N. Am., Inc. v. Nat'l Marine Fisheries Serv.*, No. 8:18-cv-00961-PWG, 2018 WL 5846816, at *6 (D. Md. Nov. 8, 2018) (citing Fed. R. Civ. P. 24(b)). When ruling on permissive intervention, a court should consider "whether the intervention will unduly delay or prejudice the adjudication of the original parties' rights." Fed. R. Civ. P. 24(b)(3). Additionally, if the party on whose side the applicant seeks to intervene would not be an adequate representative of the intervenor's interest, it weighs in favor of granting permissive intervention. *See Makhteshim Agan*, at *6. Lannett meets both elements for permissive intervention and its joining this action would not cause any undue delay or prejudice.

1. This Motion to Intervene Permissively Is Timely, and There Is No Undue Delay or Prejudice.

For the same reasons as stated above, Lannett's motion to intervene is timely. The complaint was filed on November 12, 2020. There have not been any significant filings made since that time. Additionally, Lannett's entry into this case would not cause prejudice to any of the parties currently named. Rather, Lannett's intervention would "promote judicial and administrative convenience by avoiding a multiplicity of proceedings and by bringing to the aid of the tribunal the parties who 'may know the most facts and can best explain their implications.'" *See Textile Workers Union of Am., CIO v. Allendale Co.*, 226 F.2d 765, 770 (D.C. Cir. 1955).

2. There Are Common Questions of Law and Fact.

Both Genus's and Lannett's interest in this case lie with the status of the Lannett NDA. While Genus seeks to compel FDA to take actions to invalidate the NDA's approval, Lannett seeks to preserve that approval and to clear its name that has been improperly smeared by the allegations in the complaint. The facts and legal issues required to resolve this case are common to both Genus and Lannett.

V. CONCLUSION

For the reasons stated above, the Court should grant Lannett's motion to intervene in this action as a defendant, and should permit Lannett to answer or move against the complaint on the same date that the Federal Defendants' answer or motion is due. Lannett has meet all requirements for intervention under Fed. R. Civ. P. 24(a) as well as under Fed. R. Civ. P. 24(b). Genus does not oppose this motion, and the Federal Defendants take no position as to this motion.

December 14, 2020

Respectfully submitted,

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